Durham VAMC IRB: Initial Review Form Descriptions

IRB Submission Checklist: This form must be completed by the Investigator prior to submitting a study for initial review. It can be used as a guide to determine what forms are required for an initial review. All items must be addressed.

Page 18 Investigator Data: Page 18 is required for new Principal Investigators (PIs) or Co-Investigators only. If the PI has submitted a Page 18 for a prior study, do not re-submit. PIs must be VA faculty (full time, part time, or WOC). Medical residents, fellows, pharmacy students, and nursing students must contact the Research Office prior to a protocol submission. Note: If you are submitting a Page 18, you should also include a current resume.

Initial Request to Review Research: This form is required and must be signed by the Section/Service Chief or it will not be submitted to the IRB for review. Complete all applicable items. Funding source must be included (write 4 digit number and sponsor name). If unfunded, use code 0000 and identify as none or pending sources. Once funded, you must notify the Research Office (See Request to Review Funding Source Codes).

Request to Review Funding Source Codes: Use this document to identify funding source codes.

Protocol Guidance: This document provides guidance on how to write a research protocol. Two protocols may need to be submitted—a main (sponsor) protocol and a local protocol that is Durham-specific for the procedures/research that will be done at the Durham VAMC.

Staff Listing: The mandatory Staff Listing provides a list of all personnel who conduct any part of the research endeavor and must include the names of all individuals either involved in the conduct of the study or who make decision regarding study procedures.

Conflict of Interest Statement: All Investigators (including co-Investigators or sub-Investigators) must complete this form at initial review, continuing review, and any time there are conflict of interest changes during the course of the study.

Checklist for Reviewing Privacy, Confidentiality, and Information Security: The Privacy Officer (PO) and Information Security Officer (ISO) reviews should occur **prior** to IRB submission. The Checklist and supporting documentation should be completed, signed by the PI, and simultaneously submitted electronically to the PO and ISO. **Do not** submit your application to the IRB until you have made all corrections and have signed approval from the PO and ISO.

Appendix G: This form concerns safety issues for the research team and is required when the study involves biological, chemical, physical, or radiation hazards. If the study involves any sample collection, transport, or processing by the VA clinical laboratory, the form is not required, as there are no concerns for the research team.

Durham VAMC IRB: Initial Review Form Descriptions

Exemption Application: Complete this application if the research is not human subject research and may be exempted from IRB review (note that at a minimum, R&D review will be required).

Form 10-9012: This form is required for each investigational drug, if applicable.

Form 10-3203: When the research subject is a patient (either an inpatient or outpatient), this form is required to permit photographs or video and voice recordings that will be used for research purposes even if the IRB has waived the requirement for documentation of informed consent for research.

*Reminder: An abstract must also accompany your protocol and initial submission.

Informed Consent and HIPAA Documents (unless waived, all human studies require informed consent and HIPAA authorization)

Informed Consent Form (ICF) Template: Use this template for all new studies submitted after March 31, 2011.

HIPAA Authorization Template: Use this template for all new studies submitted after March 31, 2011.

ICF Radiation Risk Statements: If the research involves radiation risks, this document provides template language to describe various procedures involving radiation.

Waiver or Alteration of the Informed Consent Process: Include if you are requesting a waiver or alteration of the required elements of informed consent (or if you want to screen and recruit prior to obtaining informed consent and HIPAA authorization).

Waiver of Informed Consent Documentation: Complete this form if you wish to waive written informed consent and the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., verbal consent for phone surveys).

- An adequate informed consent *process* must be provided regardless of whether or not the subject signs an informed consent form.
- Submit a script of the language that will be presented to the subject when the study is explained.
- A research consent note documenting the subject's agreement to participate must be placed in CPRS or a paper record for non-veterans/employees. Note: the research consent note is not required if the waiver was approved secondary to a potential breach of confidentiality.

Waiver or Alteration of HIPAA Authorization: Submit if you are requesting to waive or alter elements of HIPAA Authorization (or if you want to screen and recruit prior to obtaining informed consent and HIPAA authorization).

Durham VAMC IRB: Initial Review Form Descriptions

Safety/SRS Forms (complete forms as applicable)

Human Blood, Tissue, or Cell Line SOP: This form is required if human samples are collected or transported by the research staff, or if human samples are processed and or analyzed in a research laboratory.

rDNA Form: This form is required if the protocol includes the generation of recombinant DNA.

Viral Vector Registration: This form is required if the protocol includes the use of viral vectors for recombinant DNA purposes.

Transporting/Shipping Biological Specimens SOP: If research personnel package or ship biological samples, they must receive specific training and provide documentation with the initial submission.

Particularly Hazardous Substance (PHS) Approval Form: If the research requires the use of a particularly hazardous substance, the PI must first complete this form and receive approval from the Research Industrial Hygienist prior to purchase/first use. Please see the key at the end of the document for more information.

Standard Operating Procedure (SOP) for each particularly hazardous substance (PHS): Once you have approval to purchase/use a PHS, the PI must complete this SOP and have all relevant personnel sign and date the form. Please see the key at the end of the document for more information.

Standard Operating Procedure (SOP) for Gas Anesthetic Waste Scavenging: The PI must sign and date this SOP if the research requires the use of F/air canisters for anesthetic waste scavenging.

Department of Defense and/or Education Forms (only required for DoD- or ED-funded research)

DoD Supplement: This supplement must be submitted for all DoD-funded studies.

ED Supplement: This supplement must be submitted for all ED-funded studies.

ED FERPA Compliance: Complete this document to determine whether personally identifiable information (PII) can be released from study educational records.

ED School Permission to Conduct Research: Cut and paste this information into a letter and provide letter (and other relevant study materials) to school official(s) to obtain permission from schools at which your research will be conducted.

Durham VAMC IRB: Initial Review Form Descriptions

Data Repository Forms

Application to Establish a Research Data Repository: Complete this form if you wish to create a new research data repository. Note that you will also need to complete standard operating procedures for the research data repository.

Application to Use Data from a Data Repository: Complete this form if you wish to use data from an existing data repository.